BEFORE THE AMERICAN ARBITRATION ASSOCIATION

North American Court of Arbitration for Sport Panel

United States Anti-Doping Agency,	)	
	)	
Claimant,	)	
v.	)	
	)	AAA No. 30 190 00847 06
Floyd Landis,	)	
	)	
Respondent	)	
	)	

THE UNITED STATES ANTI-DOPING AGENCY'S PRE-TRIAL RESPONSE BRIEF

I. INTRODUCTION

1. As the United States Anti-Doping Agency ("USADA") made clear in its Pre-Hearing Brief, the Laboratoire National de Dépistage du Dopage ("LNDD") confirmed the presence of exogenous testosterone in Respondent's A and B samples by Isotope Ratio Mass Spectrometry ("IRMS") analysis. USADA made equally clear that Respondent's elevated testosterone/epitestosterone ("T/E") ratio, which was so different than his historical longitudinal profile, was strong corroborating evidence. The further IRMS analysis of Respondent's other seven Tour de France ("Tour") samples, which found evidence of exogenous testosterone in four samples, is also strong corroborating evidence.

2. As has been noted by several Court of Arbitration for Sport ("CAS") Panels, IRMS and T/E ratio analysis are two completely separate and independent laboratory methods for identifying exogenous testosterone use. Either method can stand alone as proof of an adverse analytical finding. (See Susin v. Federation Internationale de Natation Amateur (FINA), CAS 2000/A/274 at paragraph 151; World Anti-Doping Agency v. Wium, CAS

2005/A/908 at paragraph 2.14 attached at Exhibits 14 and 16; World Anti-Doping Code 2006 Prohibited List (Exhibit 5); WADA Technical Document TD2004EAAS, and the discussion starting at paragraph 118 of USADA's Pre-Hearing Brief.)

3. Given that LNDD's adverse analytical finding was based on the IRMS results, it is telling that Respondent focused 48 pages of his Pre-Trial Brief on T/E ratio analysis and dealt with the IRMS results almost as an afterthought. The reason for this imbalance is obvious; after having LNDD's 370 page documentation package for eight months, and requesting and receiving 1588 pages of additional laboratory documentation from LNDD, Respondent currently has no legitimate basis to dispute the validity of LNDD's IRMS results.

4. Concerning IRMS, the Panel will be presented with two issues: (1) Are LNDD's IRMS results for this sample reliable?, and (2) Do these results meet the conditions for a positive test? On the first issue, USADA's Pre-Hearing Brief provided detailed evidence of contemporaneous and historical quality control results which demonstrated that LNDD's results for Respondent's A and B samples must have been accurate because all of the controls run at the same time can be proven to be accurate. In his 99 page Pre-Trial Brief, Respondent offers not a word of reply to the reliability of LNDD's quality control results and the necessary corollary that Respondent's sample results are, therefore, also reliable. Other than hoping to pull a rabbit out of a hat by reserving the right to comment on the electronic data files, Respondent simply cuts and pastes the "outdated software" and "operating pressure" arguments from his Discovery Brief to which USADA has already responded. (See discussion starting at paragraphs 98 and 105 of USADA's Pre-Hearing Brief.) Respondent also attempts to reserve the right to address what he generally refers to as IRMS problems involving linearity, stability, laboratory procedures, instrument maintenance, and reliability of data "upon receipt and review of the data to which he

is entitled." As the Panel is well aware, USADA has been asking Respondent to identify his defenses since well before our first status call with the Panel.[1] The Panel directed by its Order of March 23, 2007, that USADA would finally learn all of Respondent's defenses with the filing of his Pre-Trial Brief on April 25, 2007[2]. USADA trusts that the Panel will have little patience if Respondent attempts to attack LNDD's IRMS analytical results with new arguments other than those arguments which come from the electronic data files or the SOPs which were recently provided to him.

5. In two very important respects the reliability of LNDD's Stage 17 IRMS results is strongly corroborated by the further analysis of Respondent's other seven Tour B samples. First, Respondent's claim that he is not a doper, and that the Stage 17 results must be a laboratory mistake, is undercut by the fact that four of his other seven Tour samples also contained evidence of exogenous testosterone use. Second, Respondent's claim that LNDD's Stage 17 IRMS results were erroneous because LNDD used outdated OS2 software, instead of newer MassLynx software, is undercut by the fact that the further analysis of Respondent's samples was performed at LNDD on a second Isoprime instrument operating on new MassLynx software. This is important not just because Respondent's samples showed evidence of testosterone using the MassLynx software touted by Respondent's expert, it is also particularly

[1] USADA requested this information on numerous conferences, both with opposing counsel and the Panel. See also correspondence dated March 19, 2007 (Exhibit 95). USADA is continuing its consecutive numbering from its Pre-Hearing Brief. As such, the exhibits are: Pre-Hearing Brief (USADA Exhibits 1-49); Response to Respondent's Motion in Limine regarding further analysis (USADA Exhibits 50-94); Pre-Trial Response Brief (USADA Exhibits 95-109).

[2] During the conference call with the Panel on March 21, 2007, USADA had again raised the issue of not being subject to surprise defenses. At that time, the Panel clarified that all defenses were to be set out in Respondent's response brief.

important because the quality control results for the same Mix Cal Acetate, Blank Urine and Mix Cal IRMS controls using both the OS2 and MassLynx software are consistent.

6. Respondent makes two assertions with respect to the second question before this Panel. First he claims that the WADA-accredited laboratories at UCLA, Sydney and Cologne would all report his sample negative. Contrary to Respondent's assertion, USADA will call the directors of all three laboratories and each will say that LNDD's delta/delta value results for Respondent's sample would be considered positive in their laboratory. Second, Respondent faults LNDD for simply accepting the WADA positivity criteria of -3 delta/delta units for a single metabolite as set forth in WADA Technical Document TD2004EAAS instead of conducting its own validation study on that criteria. WADA laboratories are expected to establish the reliability of the numerical values which they report; however, when WADA has established a positivity criteria, they are not expected (let alone required) to conduct their own studies to validate that criteria.

7. Since Respondent's sample-bottle chain of custody defense argument is a defense which Respondent has raised for the first time in his Pre-Trial Brief, that argument will also be addressed in some detail herein.

B. <u>Respondent's Sample Testing Chronology.</u>

8. USADA in its Pre-Hearing Brief, starting at paragraph 9, has provided the Panel with a chronology, which includes sample testing. Unfortunately, the Sample Testing Chronology provided by Respondent contains so many inaccuracies that the most practical way for USADA to respond is by redlining Respondent's submittal and commenting on underlined portions. That redline follows.[3]

[3] Corrections are noted in bold or by footnote.

B. STAGE 17 SAMPLE TESTING CHRONOLOGY

1. July 20, 2006

Mr. Landis' Stage 17 A and B samples was received by LNDD at 21:35. See[4] Exhibits 22 and 24. According to LNDD records, at 22:15 the A bottle was placed in the refrigerator and the B bottle was placed in the freezer. See Exhibit USADA0253.

2. July 21, 2006

At ~~7:35~~ **7:25**, L. Martin ("Martin") removed the A bottle from the refrigerator. At 8:10, Martin prepared the aliquot for the EPO test. See Exhibit USADA0253. Between 8:10 and 9:10, LNDD has no documentation concerning the intra-laboratory transfer of the A bottle that occurred between Martin and Garcia.[5] At 9:10, Garcia prepared an aliquot for the T/E test. See Exhibit USADA0253. At 9:25, the A bottle was placed in the refrigerator. See Exhibit USADA0253. At 9:40 the T/E aliquot was sent to a chemistry laboratory. See Exhibit USADA0255. The T/E chemistry workup, described later, lasted from 9:40 to 14:45. See Exhibits USADA0037-0039, 0043. The T/E or GC/MS test (described below) was performed at 19:36 by Galatola, and was monitored by Cerpolini. Exhibit USADA0255. At an unknown time,[6] Cerpolini read the T/E data. Exhibit 0054.

3. July 22, 2006

At ~~9:25~~ **9:05**, Cerpolini removed the A bottle from the refrigerator. Exhibit USADA0253 **and 0006**. At 10:50, Cerpolini created the first confirmation T/E aliquot. Exhibit USADA0253. At 11:02, the first confirmation aliquot was sent to chemistry. Exhibit USADA0200. The first T/E aliquot was at chemistry from 11:02 to 16:00, the chemistry was performed by Cerpolini. Exhibit USADA0200. At 11:20, Mongongu prepared a GC-C-IRMS (described below) aliquot using the A bottle. Once again, LNDD has no documentation concerning the intra-laboratory transfer of the A bottle between Cerpolini and Mongongu that accurred between 10:50 to 11:20.[7] At 11:25, the IRMS aliquot is taken to the chemistry laboratory byMongongu. Exhibit **USADA0**119-**0**120. The IRMS aliquot was at chemistry from 11:25 to 19:40, which is performed by Mongongu. Exhibits USADA0119-0120. At ~~12:40~~ **12:45**, Cerpolini places the much traveled A bottle

[4] The italics from the original have been omitted.

[5] There is no WADA requirement to have documented the transfer from Martin to Garcia. LNDD documented that Martin had custody of the A bottle at pages USADA0007 (USADA Exhibit 24) and page LNDD 1590 (Exhibit 103) and that Garcia had custody of the A bottle at page LNDD 1590 (Exhibit 103).

[6] In most laboratories, it would be unusual for the time of data reading to be recorded.

[7] There is no WADA requirement to have documented the transfer from Cerpolini to Mongongu. LNDD documented that Cerpolini had custody of the A bottle at page USADA0200, and that Mongongu had custody of the A bottle at page USADA0119. (See Exhibit 24).

in the refrigerator. Exhibit USADA0253 **and 0006**. At 18:02, the first A confirmation T/E test is conducted. Exhibits USADA~~0201-0205~~**0256 and 0212**.

4. July 23, 2006

From 9:05 to ~~14:25~~**11:00**, the IRMS aliquot was in chemistry, which was performed by Mongongu. Exhibits USADA0120-0121. At 14:30, the A bottle was removed from the refrigerator by Cariou, and at 15:00 the second A confirmation T/E aliquot is made by Cariou. Exhibits USADA0253-0256. Yet again, LNDD has no documentation concerning the location or handler of the A bottle of the A bottle from 15:00 to 17:00.[8] From ~~15:10~~**15:00** to 17:25 the second confirmation T/E aliquot is in chemistry, which was performed by Cariou. Exhibit USADA0079. At 17:00, while Cariou performed the chemistry on the second T/E aliquot, Cariou returned the A bottle to the refrigerator. Exhibit USADA0253 **and 0006**. At 21:23 Mongongu read the data from the IRMS test.[9] Exhibits USADA0155, 0185-0186.

5. July 24, 2006

Sometime before 8:20, Cerpolini removed the A bottle from the refrigerator. Exhibit USADA0253 **and 0006**. At 8:20, Cerpolini placed the A bottle in the freezer. Exhibit USADA0253. From 9:10 to 10:54, chemistry continued on the second T/E confirmation test by Cariou. Exhibit USADA0079. Sometime after 12:54, ~~Cerpolini read the data from the first confirmation T/E test.~~ [10]Exhibits USADA0212-0215, 0223. At 13:28, the second T/E confirmation test was conducted. Exhibit USADA0256, ~~0080-0084~~**0092**. At 17:15, the second confirmation data was read by Cerpolini.[11] Exhibits USADA0092-0093, 0101.

---

[8] There is no WADA requirement to document the location of a sample bottle. The requirement to document the individual (Cariou), date (July 23, 2006) and purpose (aliquot for T/E confirmation) are met at page USADA0079. (USADA Exhibit 24).

[9] 21:23 on page USADA0155 is the time of printing, not necessarily the time Mongongu read the data. In most laboratories it would be unusual for the time of reading to be recorded.

[10] First of all, the facts as described are inaccurate. The data from the first T/E confirmation was read in time to observe a problem with the internal standard being too weak and request, on July 23, 2006 (not July 24, 2006), a repeat (second) T/E confirmation, as documented at page USADA0191. (USADA Exhibit 24). Second, the notion that the second T/E confirmation, started on July 23, would for some reason have been started the day before reading the data from the first T/E confirmation is inconsistent with both logic and logistics. To clarify, the second T/E confirmation was started only after and because the data from the first one was rejected.

[11] In most laboratories it would be unusual for the time of reading to be recorded.

6. July 25, 2006

At ~~a time unknown~~ **10:42 (USADA0058)** based on the documentation, ~~Buissiou~~ **Buisson** re-~~conducted~~**injected** ~~either~~ the ~~first or~~ second[12] A T/E confirmation aliquot using the screen method. Exhibits USADA0057-0059.

7. July 28, 2006.

There is no documentation concerning when the B bottle was removed from freezer 3, by whom the bottle was removed, and where the bottle was located after it was removed. At 15:45, the unknown operator replaced the B bottle in freezer 5.[13] Exhibit USADA0254.

8. August 3, 2006

At 9:12, the B bottle was removed from the freezer by Cerpolini. Exhibit USADA0251 **and 0299**. At 11:03, Frelat creates the B IRMS aliquot. Exhibit USADA0254 **and 0299**. LNDD has no documentation concerning the intra-laboratory transfer of the B bottle from Cerpolini to Frelat which occurred sometime between 9:12 and 11:03.[14] At 11:05, Barlagne creates an aliquot for the B T/E test. Exhibit USADA0254. LNDD has no documentation concerning the intra-laboratory transfer of the B bottle between Frelat and Barlagne.[15] From 11:26 to 18:05, the B IRMS aliquot is in chemistry, which is performed by Frelat. Exhibits USADA0299-0300, 0106-0109. From 11:45 to 16:25, the B T/E aliquot is at chemistry, which is performed by Barlagne. Exhibits USADA0264, 0074-0076. ~~At 19:45~~**Beginning at 18:43**, the B T/E test is conducted. Exhibits USADA0256, 0265-0268, 0272, **0277, 0279, 0281**.

9. August 4, 2006

At 7:39, the B T/E test data was read by Barlagne and Cerpolini. Exhibits USADA0269-0271, 0277-0284, 0288. Frelat continued to perform chemistry on the B IRMS aliquot

---

[12] Again, the first T/E confirmation data was rejected because the internal standard was too weak. Continuing to analyze that vial would have been nonsense. In addition, it is clear from comparing the data at pages USADA0057-0058 (reinjected vial), 0092-0093 (second T/E confirmation vial), and 0212-0213 (first T/E confirmation vial, gave data that was rejected) (USADA Exhibit 24), specifically the relative counts of testosterone and methyltestosterone internal standard, that it is the second T/E confirmation vial that was reinjected.

[13] The B bottle was moved from Freezer 3 to Freezer 5 by F Neveu V8, as documented on page USADA0254. (USADA Exhibit 24).

[14] There is no WADA requirement to have documented the transfer from Cerpolini to Frelat or from Frelat to Barlagne. LNDD documented that Cerpolini had custody of the B bottle at page USADA0251, that Frelat had custody of the B bottle at page USADA 0299, and that Barlagne had custody at page USADA0264. (USADA Exhibit 24).

[15] See previous footnote.

from ~~9:16~~ **9:14** to ~~16:40~~**17:00**. At 17:00 Frelat conducted the IRMS test. Exhibit USADA**0300**-0302. At a time unknown, Frelat read the IRMS data.[16] Exhibits USADA0351-0352. (Respondent's Pre-Trial Brief at 7-11).

C. Respondent's Introductory Arguments.

9. The heart of this case is Respondent's positive test. The issue is not whether Respondent's Stage 17 comeback was a superhuman effort or whether he, or any cyclist, would be wise to take exogenous testosterone. USADA simply makes the following brief points with respect to the opening section of Respondent's brief:

a. It is not an anti-doping agency's burden to establish how a prohibited substance entered an athlete's body or that the prohibited substance found could have been performance-enhancing in that sport. (See, e.g., Aanes v. Fédération Internationale des Luttes Associées (FILA), CAS 2001/A/317 at V.2.1; Leipold v. FILA, CAS 2000/A/312 at paragraphs 64-66 attached as Exhibits 96 and 97.) Furthermore, recent test results seem to show that elite cyclists believe they get some benefit from testosterone and other anabolic. Over the last five years in UCI testing alone 67 cyclists have been found to have committed doping violations involving anabolic steroids, including 19 for exogenous testosterone. (See Exhibit 98.)

b. Respondent specifically argues that it made no sense for him to take testosterone only on the day of the 17th Stage. As USADA explains in its Response Brief Regarding the Further Analysis of Respondent's Other Seven Tour B Samples ("Further Analysis Response Brief"), the further analysis of Respondent's other seven B samples from the Tour provides reliable evidence that Respondent used exogenous testosterone during much of the

[16] As Respondent's observer Dr. de Boer should be able to confirm, Frelat read the IRMS data not on August 4, 2006, but on August 5, 2006. She immediately brought the data Dr. de Boer for his review.

Tour. Because none of Respondent's pre-Tour samples were analyzed by IRMS, there is also no way to know whether the Tour was the first time that Respondent used exogenous testosterone. USADA's Further Analysis Response Brief and the Exhibits to that brief are incorporated herein by reference.

c. Finally, at page 7 of his Pre-Trial Brief, Respondent states, "On August 5, 2006, LNDD notified Mr. Landis, USADA, the AFLD, the UCI and the media of its findings." (See Exhibit GDC0006.) The inaccuracy of Respondent's statement is exposed by his own exhibit. Exhibit GDC0006 is a press release from UCI, not LNDD, that Respondent's B sample confirmed the A sample result.

II. BURDEN OF PROOF.

A. The UCI Rules.

10. The applicable burden of proof is clearly set forth in UCI Rules 16, 18 and 19 which are among the mandatory articles of the World Anti-Doping Code ("World Code") that UCI has incorporated essentially verbatim. (The UCI Rules are Exhibit 1 to USADA's Pre-Hearing Brief. The World Code is Exhibit 4 to USADA's Pre-Hearing Brief. (See Article 3, page 12, and Introduction, page 6.)

B. The Presumption in Favor of WADA-Accredited Laboratories.

11. The presumption in favor of WADA-accredited laboratories is set forth below in UCI Rules 18 and 19.

> "**18.** *WADA*-accredited laboratories or as otherwise approved by *WADA* are presumed to have conducted *Sample* analysis and custodial procedures in accordance with the *International Standard* for laboratory analysis. The *Rider* may rebut this presumption by establishing that a departure from the *International Standard* occurred.

"If the *Rider* rebuts the preceding presumption by showing that a departure from the *International Standard* occurred, then the UCI or the National Federation shall have the burden to establish that such departure did not cause the *Adverse Analytical Finding*.

"**19**. Departure from these Anti-Doping Rules, the *Procedural Guidelines* set by the Anti-Doping Commission or the *International Standard* for *Testing* which did not cause an *Adverse Analytical Finding* or other anti-doping rule violation shall not invalidate such findings or results. If the *Rider* establishes that departures from these Anti-Doping Rules, the *Procedural Guidelines* or the *International Standard* occurred during *Testing* then the UCI or its National Federation shall have the burden to establish that such departures did not cause the *Adverse Analytical Finding* or the factual basis for the anti-doping rule violation."

Respondent's description of these two rules as requiring a three-step approach is essentially accurate: (1) The laboratory results are presumed accurate; (2) unless the athlete can establish that a departure from the International Standard for Laboratories ("ISL") occurred (English version at USADA Exhibit 8. French version of the ISL at Exhibit 99); and (3) if there was a departure from the ISL, then the anti-doping organization must establish that such departure did not cause the adverse analytical finding.

12. While Respondent relates the correct process for the shifting burden, Respondent then seeks to entirely alter the burden of proof contained in the final shift. First, Respondent correctly concedes that if Respondent establishes a violation of an ISL Standard, the burden shifts back to USADA to show that the violation "did not cause the Adverse Analysis Finding." (Respondent's Pre-Trial Brief at page 23) (Emphasis added.) However, Respondent then attempts to create a new unprecedented standard. Respondent asserts at page 24 of his Pre-

Trial Brief that to meet its burden USADA must show that any non-conformity with the ISL "did not, even in the slightest fashion, affect its test results." Respondent's attempt to create a new standard flatly fails, because it is entirely unsupported by the express language of the ISL.

13. At footnote 10 of his Pre-Trial Brief, Respondent challenges the following statement in USADA's Pre-Hearing Brief, as being unsupported. "As a matter of policy, this presumption is supported by the fact that one of WADA's core responsibilities is to monitor the laboratories that is accredits and to ensure that those laboratories are also certified by the ISO." WADA's extensive accreditation and re-accreditation requirements are set forth in detail in the ISL. (See, e.g., ISL (Exhibit 8) Articles 4.0 and 6.0.) If it is not because of WADA oversight, why else would the World Code only extend this presumption to those laboratories that are "WADA-accredited or otherwise approved by WADA"? The logical connection between the WADA oversight process and the presumption in favor of WADA-accredited laboratories is entirely consistent with the bedrock principle that it is for WADA and ISO to monitor laboratories and it is not a job best left to individual arbitration panels, except in the rare circumstance when a specific violation of the ISL can be established.

C. Alleged mistakes in connection with the analysis and documentation of Respondent's T/E ratio do not make the IRMS results "wholly meaningless."

14. As noted in USADA's Pre-Hearing Brief, T/E ratio analysis using the GC/MS instrument and IRMS analysis using the GC/IRMS instrument are separate and independent means of proving the presence of exogenous testosterone. The methods are performed separately in the laboratory by different laboratory personnel. Because the methods are separate, any deviation from the ISL which Respondent alleges occurred during the T/E analytical process could not cause the adverse analytical finding based on IRMS. LNDD reported Respondent's sample as an adverse analytical finding for exogenous testosterone based

on LNDD's IRMS confirmation results. LNDD's adverse analytical finding report mentions the T/E ratio but clearly states that it is IRMS analysis alone that indicates an exogenous origin for testosterone metabolites. USADA made clear in its Pre-Hearing Brief (at paragraph 27) that the confirmation of exogenous testosterone in Respondent's sample was based on IRMS and that the T/E ratio results were corroborating evidence. Respondent's Pre-Trial Brief acknowledges that, "LNDD's confirmation test is the IRMS test" (Respondent's Pre-Trial Brief page 79). Finally, to the extent USADA has a burden beyond the applicable CAS precedent to show that LNDD's T/E ratio and IRMS methods are separate and independent, that burden can be easily met.

D. The Comfortable Satisfaction Standard.

15. Article 16 of the UCI Rules, which is incorporated essentially verbatim from the World Code, provides:

> "**16.** The UCI and its National Federations shall have the burden of establishing that an anti-doping rule violation has occurred. The standard of proof shall be whether the UCI or its National Federation has established an anti-doping rule violation to the comfortable satisfaction of the hearing body bearing in mind the seriousness of the allegation which is made. This standard of proof in all cases is greater than a mere balance of probability but less than proof beyond a reasonable doubt. Where these Anti-Doping Rules place the burden of proof upon the *Rider* or other *Person* alleged to have committed an anti-doping rule violation to rebut a presumption or establish specified facts or circumstances, the standard of proof shall be by a balance of probability."

Respondent is simply incorrect in claiming that, "When the allegation of doping is minor, the anti-doping organization must present evidence that establishes that, more likely than not, the doping violation occurred" (Respondent's Pre-Trial Brief at 21) and that the burden in this case

"must be as close to 'proof beyond a reasonable doubt' as possible." (Respondent's Pre-Trial Brief at 23). Respondent simply ignores the UCI Rule which says that in all cases the standard is greater than a mere balance of probability but less than proof beyond a reasonable doubt.

16. Respondent is also incorrect in concluding that this must be the most serious alleged anti-doping rule violation because he won the Tour de France and has generated substantial public interest through his elaborate press campaign. The UCI Rule ties the level of proof required to the "seriousness of the allegation which is made." The allegation here is that Respondent committed a first anti-doping rule violation involving a positive test for testosterone. Accordingly, the same level of proof should apply in this case that would apply to any case involving a first positive test for testosterone or other anabolic steroid. To have a different standard of proof applicable to winners vs. eighth place finishers; big events (in the eyes of the world but not necessarily in the eyes of the participants) like the Tour de France vs. Olympic Trials in badminton; famous athletes like Mr. Landis vs. those athletes who toil in obscurity; or athletes who attack the system by trying their case in the press vs. athletes who focus their resources on the arbitration process, would be both unfair and totally contrary to the World Code's express goal of harmonization (USADA Exhibit 4; see, e.g., World Code Introduction, page 1, Introduction, page 2, Comment to Article 10.2 at page 26).

17. Respondent's Pre-Trial Brief refers to the Tim Montgomery case. In that case USADA was seeking a four-year ban based on an allegation of trafficking and was relying on evidence other than a positive test. The specific issue before the Panel was whether the old IAAF "beyond a reasonable doubt" standard applied or whether the new IAAF rule based on the World Code's "comfortable satisfaction" standard applied. The Panel concluded that based on their review of the specific facts of that case that there was "little difference" between the two

Standards for the purpose of deciding whether Mr. Montgomery committed a non-analytical doping violation. See also French v. Australian Sports Commission, (Exhibit 100 at ¶ 42). (Panel similarly found that where a trafficking charge was alleged "a very high standard almost approaching beyond a reasonable doubt is required.")

18. In improperly arguing for the "most stringent burden permitted by the rules" Respondent seeks to rely on a sentence from Montgomery; "the more serious the allegation, the less likely it is that the alleged event occurred." See United States Anti-Doping Agency v. Montgomery (Exhibit GDC0151). This phrase, lifted from a factually dissimilar non-analytical case, provides no support for Respondent's quest to elevate the burden in his case. Respondent's argument essentially is reduced to a claim that because he is an elite cyclist, racing for a team such as Phonak, and won the Tour de France that is somehow less likely that he was doping. To the contrary, the evidence at hearing will establish that to the extent those facts suggest anything, it certainly is not that his doping is less likely.

19. The allegation against Respondent is that he committed a doping violation because the IRMS analysis of Stage 17 sample confirmed that he used exogenous testosterone. In the context of anti-doping and unfortunately, cycling, there is nothing unique about this case. Certainly the fact that Respondent's doping led to success cannot be offered as the reason to give him the benefit of a heightened standard.

III. LNDD'S SAMPLE BOTTLE CHAIN OF CUSTODY SATISFIES WADA CRITERIA.

20. Respondent is now claiming for the first time that there are numerous deficiencies in LNDD's A bottle chain of custody and B bottle chain of custody.[17] These claims must be what Respondent's counsel had in mind when he told the Panel during the February 22 discovery hearing that "we didn't want to lay the entirety of our case out." (Exhibit 101). Respondent's chain of custody claims are misplaced.

21. The WADA ISL and WADA Technical Document TD2003LCOC set the applicable standard for laboratory chain of custody. Respondent's claim that USADA cannot establish chain of custody "beyond a shadow of a doubt" (Respondent's Pre-Trial Brief, paragraph 25) and Respondent's reference to a 1992 article (a dozen years before WADA promulgated the ISL) for the proposition that laboratory chain of custody must be "impeccable" are simply hyperbole. The applicable requirements for laboratory chain of custody are set forth in ISL Section 5.2.2.2 (see Exhibit 8) and Technical Document TD2003LCOC (Exhibit 102). As with any other section of the ISL, there is a presumption in favor of the laboratory; the athlete has the burden of establishing a departure from the ISL, and then the anti-doping organization has the opportunity to come back and show to the Panel's comfortable satisfaction that the departure did not cause the adverse analytical finding. In this case, LNDD's chain of custody documentation practice was entirely consistent with the ISL. Moreover, the individual laboratory technicians who had custody of the A and B bottles of Respondent's sample will testify as to the secure whereabouts of those sample bottles at all times.

[17] For example, bottle chain of custody is not challenged in the detailed claims of Respondent's Discovery Brief, except for allegations regarding non-forensic corrections..

22. LNDD's approach to chain of custody documentation is different than the form of documentation used by either the University of California at Los Angeles ("UCLA") laboratory or the Montreal laboratory ("Montreal"). First, LNDD uses multiple separate contemporaneous forms with a summary document prepared at the time the laboratory documentation package is assembled. By contrast, UCLA and Montreal each use a single document onto which bottle chain of custody entries are made. However, even the UCLA and Montreal forms are quite different (compare Respondent's Exhibits pages GDC0030-31 with GDC0032-33). Second, LNDD's identifies each person who had custody of a bottle individually (e.g., A, B, C, D). This contrasts with the UCLA approach which, because a single form is used, identifies the person on each side of every transfer (e.g., A to B, B to C, C to D). As below, the approaches taken by all three laboratories are acceptable under the ISL.

23. ISL Article 5.2.2.2 provides:

> "5.2.2.2 The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for *Samples* from receipt through final disposition of the *Samples*. The procedures must incorporate the concepts presented in the *WADA* Technical Document for Laboratory Internal Chain of Custody (Annex C)" *(emphasis added).*

(USADA Exhibit 8). In this case LNDD complied with the concepts presented in the WADA Technical Document. For ease of further reference, each of those concepts is separately numbered in the reference to TD2003LCOC (Exhibit 102) which follows:

> "The Laboratory Internal Chain of Custody is documentation (worksheets, logbooks, forms, etc.) that records the movement of *Samples* and *Sample* Aliquots during analysis. A Laboratory Internal Chain of Custody does not require a separate form.✓[1] Within the Laboratory, the Laboratory Internal Chain of Custody shall be a continuous

record of individuals in possession of the samples or *Sample* Aliquots.✓2 When not in an individual's possession, it should be documented that the *Sample* or Aliquot is within a controlled zone✓3 (Ref *International Standard* for Laboratories 5.4.3.2). The *Sample* or Aliquot must be in an individual's possession when in an uncontrolled or unsecured area of the laboratory. The entry into the Laboratory Internal Chain of Custody should be completed at the time that any change of possession occurs.✓4 The Laboratory Internal Chain of Custody must contain the name or initials of the individual, date of transfer, and the purpose of the transfer✓5 of possession. The individual's complete signature/name should appear in the documentation at least once.✓6

"A chain of custody is required for both 'A' and 'B' *Sample* bottles and every Aliquot prepared for a testing procedure. In the case of *Samples*, the Laboratory Internal Chain of Custody should record all movement from receipt in the Laboratory through storage and sampling to disposal ...

"Any forensic corrections that need to be made to the document should be done with a single line through and the change should be initialed and dated by the individual making the change. No white out or erasure that obliterates the original entry is acceptable.✓7

"The chain of custody, along with relevant testimony from individuals documented on the chain of custody documents, should provide a complete record of the *Sample* or Aliquot location."✓8

24. LNDD has separate forms (✓1) which identify each individual who had possession of the A or B sample bottles (✓3). These forms were completed at the time each new individual took possession of a bottle (✓4). Those forms also indicate the date each individual obtained possession and the purpose for which the individual obtained possession (✓5). Although LNDD technicians are frequently identified on forms by number, LNDD has given

Respondent a copy of a document which links the name and number of laboratory personnel and the complete signature/name of each of the seven individuals who possessed the A sample bottle and five individuals who possessed the B sample bottle can be found in the documentation at least once (✓[6]): W Rahali USADA 0013, L Martin USADA 0014, M Garcia USADA 0013, E Cerpolini USADA 0014, C Mongongu USADA 0013, M Cariou USADA 0013, F Neveu USADA 0013, C Frelat USADA 0013, R Barlagne USADA 0013. Every time one of the named individuals did not have physical possession of the bottle because they were engaged in some part of the sample analysis, the bottle was within a controlled zone (✓[3]). As defined in ISL Article 5.4.3.2.2, controlled zones are those areas of the laboratory where access is monitored and records are maintained of access by visitors. LNDD identified a number of "Salles" or rooms where technicians took either the A or the B bottle and these rooms are, in fact, within the controlled zone, which is the entire technical part of the laboratory (as opposed to the administrative offices). On the issue of whether the transferor or transferee must be identified on the same document, note that at (✓[5]) the Technical Document states that the chain of custody must contain the name or initials of the "individual" (singular), thus clearly implying that the individuals on both sides of the transfer need not be identified on the form.

25. Regarding the concept at (✓[7]), with two exceptions, there are no chain of custody documents where non-forensic corrections were made. The exceptions are page USADA 0079 of the A sample documentation package where technician Esther Cerpolini crossed out the initials of M Cariou and wrote down her own. This is because Ms. Cerpolini, not Ms. Cariou, had previously measured the pH and specific gravity. This exception does not affect the correct documentation of the individual (Cariou) date (July 22, 2006) and purpose (aliquotting for T/E confirmation) which constitute the chain of custody documentation. The

other exception is on page USADA 0007 where F Neveu started to write 154 and changed it to 15H45 as he was writing. The change made by Mr. Neveu is obvious and creates no confusion as to the custody or identity of Respondent's sample. Again this does not affect the correct documentation of the individual (Neveu) date (July 28, 2006) and purpose (pairing the A and B bottles). In any event, Ms. Cerpolini and Mr. Neveu will be called to explain the notations they made (✓[7]).

26. Finally, all of the individuals who had possession of either the A sample bottle or B sample bottle (each of whom are identified in the chain of custody documentation) will be called by USADA, if necessary, to establish the location of both the A and B bottles from receipt through storage and sampling (✓[8]). A chart which identifies the movement of the sample bottles and the associated chain of custody documentation follows (✓[2]). Additional LNDD bottle chain of custody documentation which LNDD does not normally provide with the documentation package is attached as Exhibit 103.

A BOTTLE NUMBER 995474			
Individual or Controlled Zone	**Date of transfer**	**Purpose of transfer**	**See page**
W Rahali V21	July 20, 2006	Receipt at LNDD	USADA0024 or 0229
Refrigerator CH.FR1	July 20, 2006	Storage	USADA0006
L Martin 44	July 21, 2006	Aliquot for EPO screen	USADA0007 + LNDD1590
M. Garcia 19	July 21, 2006	Aliquot for T/E and other screens	LNDD1591
Refrigerator CH.FR1	July 21, 2006	Storage	LNDD1591
E Cerpolini 18	July 22, 2006	Aliquot for first attempt at T/E confirmation	USADA0006 + 0200
C Mongongu 49	July 22, 2006	Aliquot for IRMS confirmation	USADA0119
E Cerpolini 18	July 22, 2006	Transfer	USADA0006

Refrigerator CH.FR1	July 22, 2006	Storage	USADA0006
M Cariou 28	July 23, 2006	Aliquot for second attempt at T/E confirmation	USADA0006 + 0079
Refrigerator CH.FR1	July 23, 2006	Storage	USADA0006
E Cerpolini 18	July 24, 2006	Transfer	USADA0006
Freezer CH.FR3	July 24, 2006	Storage	USADA0006
F Neveu V8	July 28, 2006	Transfer	USADA0007 + LNDD 1597 and see M-TE-03 starting at LNDD1592
Freezer CH.FR5	July 28, 2006	Storage	USADA0007 + LNDD1597 and see M-TE-03 starting at LNDD1592

B BOTTLE NUMBER 995474			
Individual or Controlled Zone	**Date of transfer**	**Purpose of transfer**	**See page**
W Rahali V21	July 20, 2006	Receipt at LNDD	USADA0024 or 0229
Freezer CH.FR3	July 20, 2006	Storage	Same individual, date and time as sample A, see USADA0006 and M-TE-03 starting at LNDD1592
F Neveu V8	July 28, 2006	Transfer	USADA0007
Freezer CH.FR5	July 28, 2006	Storage	USADA0007
E Cerpolini 18	Aug 3, 2006	B confirmation	USADA0251
C Frelat 26	Aug 3, 2006	Aliquot for IRMS confirmation	USADA0299
R Barlagne	Aug 3, 2006	Aliquot for T/E confirmation	USADA0264

IV. RESPONDENT'S PRE-TRIAL BRIEF ADDS NOTHING TO DISCREDIT THE RELIABILITY OF LNDD'S ADVERSE ANALYTICAL FINDING BASED ON IRMS RESULTS.

A. LNDD's Quality Controls.

27. The reason laboratories run quality controls during the analysis of samples is to establish that the results for those samples are reliable. This practice is not unique to anti-doping laboratories. What is unique to anti-doping laboratories, and LNDD in particular, is the number of quality controls which the laboratory runs. In its Pre-Hearing Brief, USADA went into considerable detail to explain how the Mix Cal Acetate, Blank Urine and Mix Cal IRMS controls run in the same sequence minutes before, during, and minutes after Respondent's sample produced the expected analytical results. Because the IRMS instrument was accurate in measuring all of the controls, the results for Respondent's samples, which were analyzed by the IRMS instrument at the same time, must also be accurate. Remarkably, Respondent's Pre-Trial Brief does not even attempt to address the significance of LNDD's simultaneous quality control results or the fact that these quality control results were also consistent with the historical results obtained by LNDD when analyzing the same quality controls.

B. There is no problem with LNDD using OS2 software.

28. Respondent's Pre-Trial Brief includes a virtually verbatim repetition of the "outdated software" and "operating pressure" arguments from Respondent's Discovery Brief. The first argument (that the OS2 software used by LNDD on its Isoprime instrument was not designed for the instrument and is outdated) is the foundation for Respondent's request to have the electronic data generated on the OS2 software reanalyzed on newer MassLynx software. During the discussion of this issue during the February 22 discovery conference, the Panel Chair suggested that the Parties might consider contacting the instrument manufacturer to see if it had already addressed the software issues raised by Respondent. USADA has, in fact, gone to

MicroMass (now GV Instruments ("GVI")) for its opinion. The GVI opinion refutes Dr. Davis's central premise that the Isoprime instrument and OS2 software are not compatible and that an Isoprime instrument operating on OS2 software is less reliable than an Isoprime instrument operated on MassLynx software. GVI also refutes Dr. Davis's specific arguments as to why the MassLynx software would be preferable to the OS2 software used by LNDD in this application. GVI's response to Dr. Davis's statement and Respondent's allegations concerning "improper operating pressure" was submitted by Timothy Brockwell, a GVI Development Scientist who has worked with MicroMass/GVI continuously since 1996. Because GVI's response so clearly addresses the central premise upon which Respondent seeks to attack LNDD's results and the premise upon which Respondent seeks to have LNDD's electronic data analyzed on MassLynx software, USADA is incorporating a substantial portion of Mr. Brockwell's statement into the text of this brief.

> "I have been supplied with and have read a copy of the statement of Simon Davis which is attached, and have been referred specifically to paragraphs 13 and 16 (and to associated paragraphs which refer to the matter mentioned in paragraph 16) of this statement and the following comments are restricted solely to these parts of Dr. Davis' statement. I cannot make any comment on the method of operation of the Paris Instrument by the Paris Lab or its state or condition at that time, or the circumstances of the analysis of any sample, as I have no personal knowledge of these facts. Neither can I make any comment on the apparent results of any such analysis as this is both beyond my personal knowledge and my area of competence and expertise.
>
> "I can state the following (the following numbering corresponds to the numbering and paragraphs referenced in Dr. Davis statement):
>
> "13 a. *[original statement of Simon Davis in italics]*
>
> > *"The Optima GC 1.67-2 software was originally written for the Micromass Optima IRMS and not the Isoprime IRMS instrument. This software is now 10 years old and can be identified by its code number 1.67.2.*
> >
> > "The Software substantially existed prior to the design of this instrument. In order to reduce the need to create further software or additional code,

the IsoPrime was designed from the outset to be compatible with the Software.

"13 b. *Since version 1.67.2 of software was produced, there have been six major version releases of software for the Isoprime. These include (1) Version 1.67-3 (OS2 operating system) (2) Version 1.67-4 (OS2 operating system), (3) Masslynx Version 3.5i (Windows NT) (4) Masslynx Version 3.6i (Windows NT), (5) Masslynx version 4.0 (Windows XP), and (6) Ion Vantage Version 1.0 (Windows XP).*

"I am aware of the releases mentioned above. The general policy of the owners of the business over the relevant period has been to offer software upgrades to customers who report a problem for which the business identified the software as the probable cause. I am not aware of any such problem being reported by the Paris Lab.

"13 c *The new versions of the software have the following improvements:*

"(i)The newer software includes a new set of electronics with a new set of firmware for the systems head amplifier that corrected errors in the OS2 head amplifier firmware.

"The head amplifier fitted to the Paris Instrument is the same design as was fitted to the Micromass Optima and does not contain firmware. The newer software (Masslynx) included new electronics and new firmware in order that the later design head amplifier should integrate with Masslynx. These changes were not relevant for IsoPrime running OS2 software.

"ii. *the newer software has the ability to control the GC portion of the GC-C-IRMS, whereas in the OS2 versions of the software, the operator has to manually program the GC.*

"This is correct.

"iii. *The newer software traces any changes that are made to the data post acquisition. For instance, if the software is reprocessed with different integration parameters this would be recorded in all Masslynx and Ionvantage systems, but not in any OS2 systems.*

"This is correct. However, in the 082 software the original data file cannot be manipulated.

"iv. *The newer software contains a standards library, for the automated storage and retrieval of standards values and data. OS2 requires the standards to be applied manually post acquisition.*

"This is correct. However, the standards library is not designed for nor is it routinely used for GC IRMS data.

"v. *The newer software has fully documented and tested background subtraction routines. The method and validity of the background routines in the OS2 software is unknown and undocumented. All documentation of the OS2 routines was lost when Micromass purchased Isotech (the developers of the original software).*

"The first sentence of this statement is correct. The presence or absence of documentation and testing of a background subtraction routine does not imply fitness for purpose. In the development of a background subtraction routine it is only practicable to test a limited number of test cases, this does not guarantee correct operation for all data sets. The onus lies with the customer to verify the correct operation of the data processing within their analytical validation protocol.' However, routine checks run by customers on QC standards of known composition will identify any inaccuracy in background subtraction routines. The method and validity of background subtraction routines would normally be validated by the customer's/operator's analytical protocols.

"vi. *The newer software has improved peak detection - the true nature of the OS2 detection methods is unknown as no documentation remains as to the method used.*

"This is answered in the response to item v. above.

"vii. *The newer software provides "read backs" that allow the true state of the Isoprime to be observed and recorded. The OS2 system offers no read backs.*

"A 'read back' would customarily be used by a service engineer as a diagnostic tool to aid in the diagnosis of a problem already identified by the customer/operator during QC. The 'read back' is therefore irrelevant to the correct operation of the instrument.

"viii. *The newer software works on a modern operating system for which you can obtain up-to-date anti-virus and malware software. OS2 Warp (the latest software that version 1.67.2 will run on) is no longer supported by IBM and no anti-virus or security software is available.*

"I am not able to comment on this statement and recommend that a person with the requisite knowledge and expertise is consulted.

"ix *The newer software is compatible with a number of Laboratory Integrated Management Systems. This is used for the control of results management.*

"This is correct however, this is not relevant to data acquisition or accuracy.

"16. I can confirm that the standard user manual for the IsoPrime included the reference to operating pressures mentioned in the second sentence of paragraph 14. I have not been shown detail referring to the pressures at which the Paris Instrument was apparently operated during the periods mentioned and cannot confirm these details as they are beyond my personal knowledge.

"It is correct to state that beyond certain pressures the IsoPrime, may suffer reduced sensitivity and precision in reported results. However, at 5E-6millibars this should not occur.

"However, in any event, the functional operation of such an IsoPrime will tend to be verified by results achieved by the laboratory/operator against standard samples i.e. samples for which the analytical result is already known, which the laboratory/operator will run periodically in order to establish that the instrument in question is operating correctly. In the event such samples show consistent results this is a clear indication that the instrument is operating correctly. Incorrect operation may show reduced sensitivity and precision of the reported results and increased variance values as stated in 16 a. of Dr Davis' statement. I assume the Paris Lab's routine checks on the Paris Instrument would identify any impairment of performance during the relevant period.

"There are approximately 20 other IsoPrime instruments which were manufactured and shipped which incorporate the OS2 software."

(Exhibit 104). When Mr. Brockwell states at paragraph V: "However, routine checks run by customers on QC standards of known composition will identify any inaccuracy in background subtraction routines," this is precisely what LNDD has done through its regular use of the Mix Cal Acetate, Mix Cal IRMS and Blank Urine quality controls.

29. GVI's "outdated software" argument is further undercut by the results of the further analysis of Respondent's other seven Tour samples and three samples provided by Dr. Aguilera which took place during the week of April 16, 2007 (the "Further Analysis samples"). That further analysis was conducted at LNDD on a second Isoprime IRMS

instrument operated by new MassLynx software. The Further Analysis sample results also corroborate the accuracy of the Stage 17 results because when the same quality controls were run on the two instruments, one with OS2 software and the other with MassLynx software, the results were comparable. In other words, we already knew that the Stage 17 results produced using the OS2 software were reliable because of the contemporaneous and historical quality controls; now we know that using MassLynx software makes no difference because LNDD analyzed the same quality control samples on both instruments and obtained comparable results. Figures which show the historical quality control results produced by the OS2 software together with the quality control results from the Further Analysis samples produced using Mass Lynx software are provided in the discussion of the results of the Further Analysis samples starting at paragraph 44 of this brief.

V. LNDD IS ENTITLED TO RELY ON THE WADA POSITIVITY CRITERIA ESTABLISHED BY WADA IN TD2004EAAS.

30. Under the ISL, WADA-accredited laboratories are required to validate the reliability of their methods. This validation is then reviewed in the ISO accreditation process. As previously noted, LNDD's IRMS method was specifically approved by COFRAC, the ISO certifying body in France, eight months before Respondent's A sample was analyzed. (See USADA Pre-Hearing Brief, paragraph 102 and Exhibit 26 (LNDD0089-0100).)

31. When WADA establishes a positivity criteria, WADA-accredited laboratories are not required to separately validate that criteria. Once WADA established its positivity criteria in TD2004EAAS,

> "The results will be reported as consistent with the administration of a steroid when the $^{13}C/^{12}C$ value measured for the metabolite(s) differs significantly i.e. by 3 delta units or more from that of the urinary

> reference steroid chosen. In some *Samples*, the measure of the $^{13}C/^{12}C$ value of the urinary reference steroid(s) may not be possible due to their low concentration. The results of such analyses will be reported as 'inconclusive' unless the ratio measured for the metabolite(s) is below -28‰ based on non-derivatised steroid."

(USADA Exhibit 9) that criteria became the relevant standard for interpreting LNDD's analytical results. The force of WADA positivity criteria as set forth in Technical Documents is made clear in the case of Canadian Anti-Doping Program and Christopher Sheppard.

> "53. As of 1 January 2005, the new WADA criterion for determining the presence of rEPO described in the technical document TD2004EPO is in force. Therefore, this new criterion is the relevant standard for interpreting the electropherogram generated during Mr.Sheppard's EPO analytical result."

(Exhibit 105, paragraph 53). Similarly, each WADA-accredited laboratory does not need to do its own research to establish that the presence of nandrolone or its metabolites in a quantity greater than 2 ng/ml is evidence of nandrolone use.

VI. THE MONTREAL, COLOGNE, SYDNEY AND UCLA LABORATORIES WOULD REPORT RESPONDENT'S SAMPLE AS AN ADVERSE ANALYTICAL FINDING.

32. Respondent's Pre-Trial Brief goes to great lengths to point out that different WADA-accredited laboratories use different testosterone metabolites and different ERCs in analyzing samples. This is not a demonstration of inconsistent criteria as Respondent alleges. Rather, the WADA Technical Document contemplates that laboratories may choose to analyze several different metabolites ("testosterone, epitestosterone, androsterone, etiocholanolone, the androstanediols, DHEA") and several different ERCs ("pregnanediol, pregnanetriol, cholesterol, 11-hydroxyandrosterone or 11-ketoetiocholanolone") (TD2004EAAS

paragraph 3, USADA Exhibit 9). It makes no difference which metabolite-ERC combination is used since under the WADA positivity criteria a significant difference in the delta/delta value for only a single metabolite-ERC pair establishes the use of exogenous testosterone. While it may be true, as evidenced by the Cologne and UCLA studies (USADA Exhibits 34, 34a, 35 and 36), that the more metabolite-ERC pairs a laboratory analyzes, the greater the chances it will catch a doper, that is not something about which an athlete can complain.

33. The LNDD, Montreal, Sydney, Cologne and UCLA laboratories were all performing IRMS analysis on athlete samples long before August 2004 when WADA promulgated its positivity criteria in TD2004EAAS. Without the benefit of a WADA positivity criteria, each of those laboratories did their own research to validate the positivity criteria that they were using at that time. As noted in USADA's Pre-Hearing Brief at paragraph 93, LNDD's old criteria was a ratio of the delta value of a metabolite over the delta value of the ERC greater than 1.12. The criteria used by those individual laboratories continued to evolve based on research and experience with the IRMS method. It is not surprising that laboratories were overly conservative when the IRMS method was first put into service and that they began using less conservative criteria after more experience and research. This is not unlike the evolution of the positivity criteria for EPO prior to the promulgation of the WADA standard which is discussed in detail in Canadian Anti-Doping Program and Christopher Sheppard (Exhibit 105). While it used to be true that at one time the UCLA and Sydney laboratories required a significant delta/delta difference in more than one metabolite-ERC pair to declare a sample positive, that is not true today. As will be explained in the testimony of Dr. Cedric Shackleton, one of the world's leading experts in testosterone metabolism, depending on the individual, the testosterone or precursor taken, the route of administration and the time duration after administration,

exogenous testosterone administration might only be detected in a single metabolite-ERC pair. This was confirmed in the research conducted by the Cologne and UCLA laboratories. This evidence was discussed at length at paragraph 88 of USADA's Pre-Hearing Brief. Respondent's Pre-Trial Brief offers no response to this evidence.

34. USADA will call as witnesses Dr. Ayotte, who was the primary drafter of WADA Technical Document TD2004EAAS, Dr. Schänzer, the Director of the Cologne laboratory, Dr. Kazlauskas, the Director of the Sydney laboratory, and Dr. Catlin, the Director of the UCLA laboratory. While all of these laboratories routinely measure somewhat different metabolite-ERC combinations, all of these laboratory directors will testify that, consistent with the WADA criteria, their laboratories declare adverse analytical findings based on a single metabolite-ERC combination. They will also testify that Respondent's 17th Stage sample with its 5alpha-Pdiol delta/delta values of 6.14(A) and 6.39(B) would clearly be called positive in each of their laboratories.

35. This is simply not a close case. Whether any laboratory formerly used to use, or even still uses in spite of TD2004EAAS, a depletion criteria of up to -4 delta/delta units (but with no subsequent adjustment for uncertainty) may be a topic for debate in some other case but not this case where Respondent's 5alpha - Pdiol delta/delta value exceeds -6.[18]

[18] Although not relevant to the analytical results in this case, Respondent also is wrong in concluding that LNDD would not report an adverse analytical finding if the delta value of any one of the metabolites alone (without reference to the delta value of the ERC) was less than -28 delta units. This is clearly stated at pages USADA 0186 and USADA 0352 of LNDD's documentation package (USADA Exhibits 24, 25).

VII. UNCERTAINTY

36. The issue of uncertainty was discussed in USADA's Pre-Hearing Brief starting at paragraph 90.

37. Respondent's Pre-Trial Brief claims that, "LNDD has refused to explain how it arrived at its measurement of uncertainty for any of its testing processes, including GC-IRMS" (page 94). In response to Respondent's specific request for all documents related to the calculation of the .8 measure of uncertainty for IRMS delta calculations and the Panel's draft Order of March 23, 2007, on March 30, 2007, USADA added its comment to the Panel's draft Order as follows:

> "C5. ALL DOCUMENTS that relate to the calculation of the .8 measure of uncertainty value for IRMS delta calculations.
>
> **"The Panel considers that this request is based on a review of the measure of uncertainty, and is still in progress; the Panel-appointed expert(s) shall report its findings and Claimant will produce additional documents responsive to this request."**
>
> Original validation of delta value uncertainty of (.8 and .5) attached at LNDD0451-0460.

The documents provided at LNDD 0451-0460 (USADA Exhibit 26) explain and provide validation for LNDD's IRMS measures of uncertainty for the delta value measurement of a single substance (±0.5 delta units) and for the delta/delta difference between two substances (±0.8 delta units). In his April 5, 2007 letter to the Panel, responding to the Panel's draft Order of March 23, 2007, and the changes proposed by USADA on March 30, 2007, Respondent stated:

> "With the exception of the issues raised below, Mr. Landis has no objection to either the language of the panel's proposed order, the proposed changes of the order to USADA or the production of

USADA to the Second Request for Production of Documents."

Paragraph C5 was not one of the issues raised below. LNDD went to a tremendous effort and expense to produce a level of documentation detail which is never required in doping cases. It is unfortunate that Respondent is still complaining after LNDD produced the documents which he specifically requested and to which he acknowledged he had no objection.

38. LNDD's measure of uncertainty for a single delta measurement (e.g., etio only) is ±0.5 delta units. The documents validating that determination are found at (USADA Exhibit 26) LNDD0458 – LNDD0460. The ±0.5 delta unit measure of uncertainty is based on LNDD's measurements of a Mix Cal IRMS mix (containing décane, undécane, dodécane and méthyldécanoate) 55 separate times over a 16 week period. The standard deviations for the four alkanes in the mix were 0.23, 0.17, 0.19 and 0.27. The highest standard deviation of 0.27 was multiplied times two, the product 0.54 was rounded to 0.5 to establish the measure of uncertainty for a single delta measurement.[19]

39. LNDD's measure of uncertainty for the difference between a metabolite and an ERC (e.g., etio – 11-keto) is ±0.8 delta/delta units. The documents validating that determination are found at (Exhibit 26) LNDD 0452-0457. The table provided on LNDD0456 is derived from the analysis of the same urine 30 times over a seven-month period. The columns on that table represent the delta/delta values of the four metabolites-ERC combinations which LNDD uses in its IRMS analysis. The standard deviations for the four metabolite-ERC combinations were 0.36, 0.33, 0.32 and 0.40. LNDD based its measure of uncertainty for

[19] The standard deviation times two formula for determining a measure of uncertainty comes from the ISL at Article 5.4.4.3.2.2 (USADA Exhibit 8). The 95% confidence interval, described in Article 5.4.4.3.2.2 equates to standard deviation times two.

metabolite-ERC delta/delta values on two times the 0.4 standard deviation or ±0.8 delta/delta units.

40. LNDD's ±0.8 delta unit measure of uncertainty was part of LNDD's method validation which was specifically approved by ISO. (See USADA Exhibit 24, USADA 0098.)

41. The historical quality control data which LNDD has produced during discovery in this case further supports the validity of LNDD's uncertainty measurement. For single delta value measurements see, for example, Exhibit 38 Figures 6, 7, 8 and 9. These exhibits show that for each of the four substances contained in the Mix Cal Acetate mix (etio, 11keto, 5beta diol and 5androstonal acetate) all 75 times each of the substances was measured before samples were analyzed between May 29, 2006 and October 6, 2006 the results were consistently within the ±0.5 range.

42. This is also corroborated by the results of each of the 43 times the same Blank Urine pool was analyzed between June and August 2006. (This data for the Blank Urine controls is described at page 42, paragraph 81, of USADA's Pre-Hearing Brief and USADA Exhibit 38 Figures 12, 13, 14 and 15.)

43. Most importantly, whether LNDD applies the 0.8 delta/delta unit measure of uncertainty to a metabolite-ERC measurement as indicated on 0617 or whether it does not, which is the practice of other WADA-accredited laboratories and the correct interpretation of the ISL, makes no difference in this case. The difference between the 5alpha diol metabolite and the Pdiol ERC measured in both Respondent's A and B samples (6.14 and 6.39) is well over -5.0 delta/delta units even if uncertainty of ±0.8 delta/delta units is taken into consideration.

VIII. LNDD'S ADVERSE ANALYTICAL FINDING FOR RESPONDENT'S STAGE 17 SAMPLE IS CORROBORATED BY THE FINDING OF EXOGENOUS TESTOSTERONE IN RESPONDENT'S OTHER TOUR SAMPLES.

44. As noted in USADA's Further Analysis Response Brief[20], Respondent's seven other Tour B samples were blinded by the inclusion of three additional samples provided by Dr. Aguilera. Each time LNDD conducted IRMS analysis on one of the ten Further Analysis samples, it had no way of knowing whether that sample was a sample from Respondent. Four of Respondent's seven samples contained evidence of exogenous testosterone.

45. Table 3 below sets forth the results of the Further Analysis samples.[21] The samples are listed in Table 3 by date of sample collection. (A listing of samples in the order in which they were analyzed by LNDD is found at Table 1 of USADA's Further Analysis Response Brief.) The results from Respondent's 17th Stage sample (#995474) have been included in Table 3 below in a box in order to provide chronological context. Delta/delta values greater than the WADA criteria of -3 delta/delta units are printed in bold. The LNDD documentation packages for each of the ten Further Analysis samples are attached to USADA's Further Analysis Response Brief as USADA Exhibits 84-93. Additional LNDD documentation related to the Further Analysis samples is attached as Exhibit 103, starting LNDD 1598. Respondent's Doping Control Forms for those samples are found at Exhibit 106.

[20] USADA's Response Brief to Respondent's Motion in Limine to Exclude the Results of the Further Analysis of Respondent's Other Seven Tour Samples and the attached Exhibits are incorporated herein by reference.

[21] All of the Tables and Figures referenced in this brief are attached as Exhibit 107.

Table 3

Collection Date	Blind Sample #	UCI Sample #	5alpha diol-Pdiol	5beta diol-Pdiol	Andro-11 Keto	Etio-11 Keto	LNDD Page #
7/3/2006	993865	995462	—	-1.04	0.22	-0.95	LNDD1488
7/11/2006	993856	994203	-2.91	-1.05	-0.25	-1.29	LNDD1391
7/13/2006	993855	994277	**-4.62**	**-4.09**	-1.99	-2.32	LNDD1106
7/14/2006	825425	994276	-1.01	-0.70	-1.70	-1.04	LNDD1297
7/18/2006	825428	994075	**-5.06**	**-3.56**	-1.22	-1.89	LNDD0915
7/20/2006	*******	995474A	**-6.14**	-2.15	**-3.99**	-2.58	USADA0186
7/20/2006	*******	995474B	**-6.39**	-2.65	**-3.51**	-2.02	USADA0352
7/22/2006	825429	994080	**-4.80**	-1.67	-1.36	-1.68	LNDD1012
7/23/2006	825424	994171	**-4.96**	-1.45	-0.64	-1.43	LNDD0725
Aguilera	825427	**NL1**	-1.31	-0.95	0.00	-0.94	LNDD1582
Aguilera	825426	**NL2**	-0.77	-0.88	0.32	-0.74	LNDD0820
Aguilera	825423	**NL3**	-1.21	-0.79	0.09	-0.91	LNDD1203

46. Importantly, the analysis of the Further Analysis samples was performed by LNDD on a second Isoprime instrument operating on the MassLynx software. Certainly all of Respondent's "outdated software" arguments are inapplicable to the Further Analysis samples.

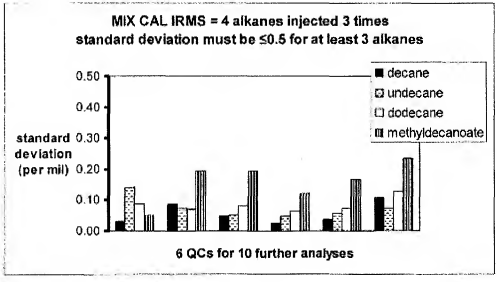
47. The reliability of the further analysis results is confirmed by the three different types of controls which were analyzed simultaneously with each of the ten samples.[22] As was demonstrated with respect to the A and B specimens of Sample 995474 in USADA's Pre-Hearing Brief, starting at paragraph 77, the analytical results for the ten Further Analysis samples must be correct because the values for the Mix Cal IRMS Control, the Mix Cal Acetate

[22] Note that four pairs of samples had the same Mix Cal IRMS and Mix Cal Acetate controls for the two samples in each pair, as follows: Blind #825429 – one set of controls; Blind #993855 and Blind #825423 – one set of controls; Blind #825426 and Blind #825428 – one set of controls; Blind #993856 and Blind #825425 – one set of controls; Blind #825427 and Blind #993865 – one set of controls; Blind # 825424 – one set of controls. Each of the ten samples had its own Blank Urine control. Therefore a total of six aliquots of Mix Cal IRMS, six aliquots of Mix Cal Acetate, and ten aliquots of Blank Urine were used for the ten samples.

Control and the Blank Urine Control all provided the expected results. As demonstrated in the Figures below, these results were also consistent with LNDD's historical results analyzing these same quality controls using the OS2 software. The results for the Mix Cal IRMS, Mix Cal Acetate and Blank Urine controls are each discussed separately below.

a. Mix Cal IRMS Controls. In connection with each IRMS analysis of an athlete's sample, LNDD injects one vial of Mix Cal IRMS which is a reference standard containing four alkanes. (See discussion in USADA's Pre-Hearing Brief starting at paragraph 77.) The Mix Cal IRMS is injected three times in a row to make sure that the triplicate results are consistent. LNDD's consistency criteria was met in the case of all ten Further Analysis samples. (The standard deviation must be ≤0.5 per mil for at least three alkanes.) Figure 22 below depicts the Mix Cal IRMS data from the Further Analysis samples analyzed using MassLynx software and LNDD's historical results for that same Mix Cal IRMS control using OS2 software.

Figure 22



b. Mix Cal Acetate Controls. LNDD's Mix Cal Acetate control is a mixture of four steroids: 5α-Androstanol, Etiocholanolone, 5β-Androstanediol and 11-Ketoetiocholanolone. The delta value of each of the four steroids in LNDD's Mix Cal Acetate control mix was previously verified by an ISO-accredited external reference laboratory, Eurofins. The exact values established by Eurofins are found at Exhibit 26, LNDD 0298, 0301, 0304, 0307. LNDD uses the Mix Cal Acetate control to check instrument accuracy. LNDD's criteria for acceptability is that at least three of the four measurements from the control must agree with the Eurofins measurement ±0.5 per mil. (See discussion in USADA's Pre-Hearing Brief starting at paragraph 77.) This criteria was met each time the Mix Cal Acetate control was analyzed in connection with the Further Analysis samples. Figures 6, 7, 8 and 9 of USADA's Pre-Hearing Brief depict historical mix Cal Acetate Control Values using OS2 software. Figures 23, 24, 25 and 26 below add the comparable Further Analysis data to those figures. The Mix Cal Acetate results from the Further Analysis samples analyzed using MassLynx software are consistent with LNDD's historical results for that same Mix Cal Acetate Control using OS2 software.

Figure 23

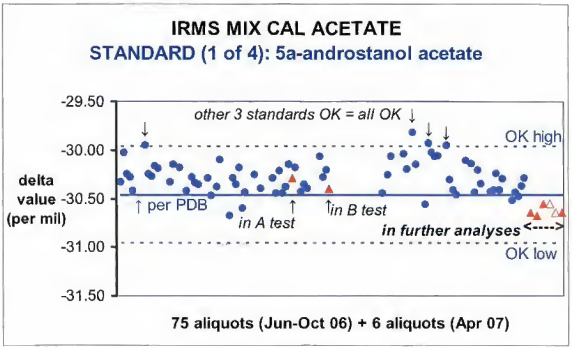


Figure 24

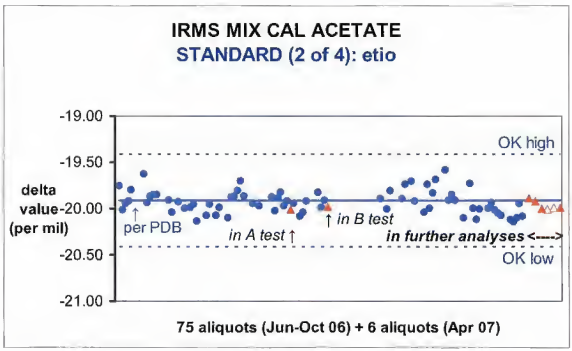


Figure 25

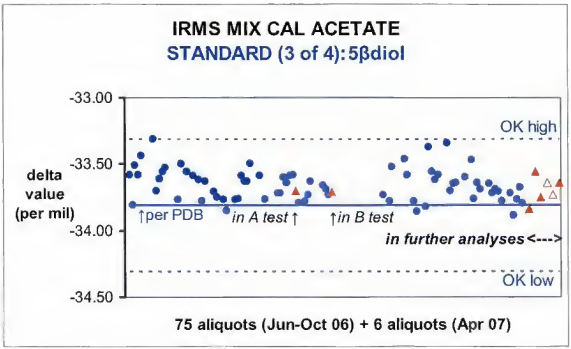
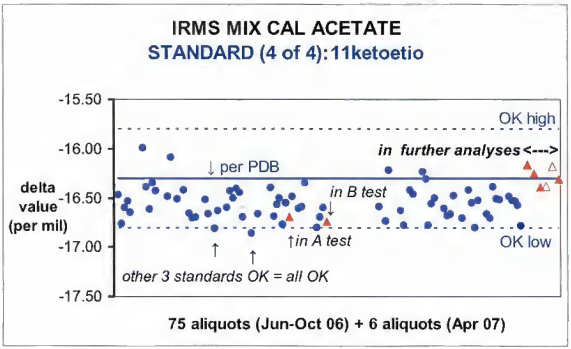

IRMS MIX CAL ACETATE
STANDARD (3 of 4):5βdiol
-33.00
-33.50
-34.00
-34.50
delta value (per mil)
OK high
OK low
↑per PDB
in A test ↑
↑in B test
in further analyses<--->
75 aliquots (Jun-Oct 06) + 6 aliquots (Apr 07)

Figure 26



c. Blank Urine Controls. LNDD checked the overall assay quality for each of the Further Analysis samples by injecting a Blank Urine from the same common Blank Urine pool each time one of the three fractions of urine from the ten Further Analysis samples was injected. Again, this was the same Blank Urine pool that LNDD used in the summer of 2006 to analyze Respondent's A and B specimens of Sample #995474. The initial delta/delta value for each of the four testosterone metabolite-ERC combinations was calculated the first time this Blank Urine pool was analyzed. At least three of the four delta/delta values for the Blank Urine must fall within ±0.8 delta/delta units of LNDD's "initial" values for the Blank Urine result to be acceptable. (See discussion in USADA's Pre-Hearing Brief starting at paragraph 77). The Blank Urine control results for all of the Further Analysis met this criteria.

Figures 27, 28, 29 and 30 below depict the Blank Urine control data from the Further Analysis samples analyzed using MassLynx software and LNDD's historical results for that same Blank Urine control using OS2 software.

Figure 27

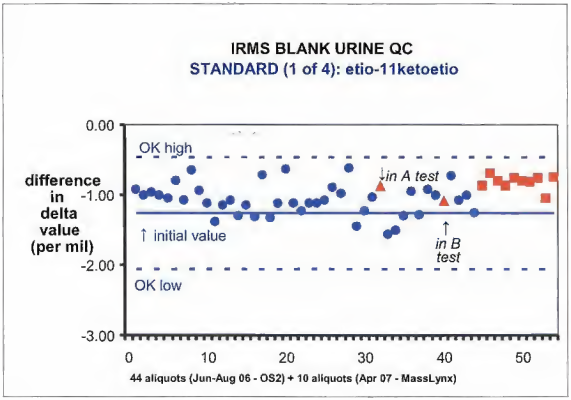


Figure 28

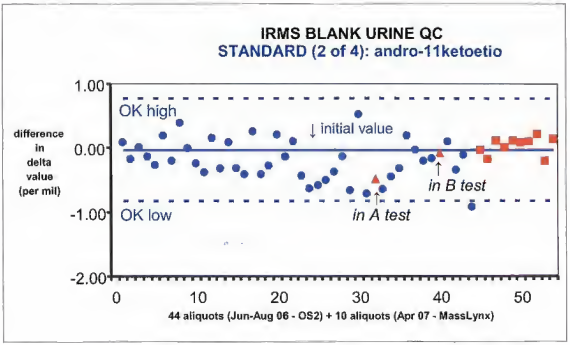


Figure 29

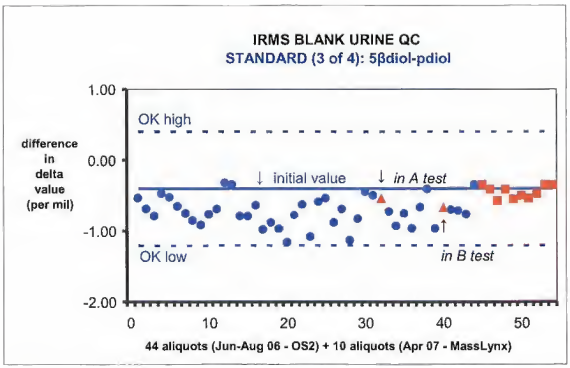
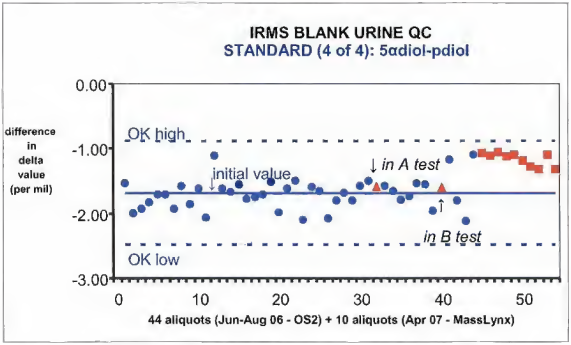


Figure 30



IX. RESPONDENT'S STAGE 17 T/E RATIO AND HISTORICAL T/E VALUES CORROBORATE LNDD'S IRMS FINDING OF RESPONDENT'S EXOGENOUS USE OF TESTOSTERONE.

48. As USADA made clear in its Pre-Hearing Brief, LNDD used IRMS, not T/E ratio, to confirm the presence of exogenous testosterone in Respondent's Stage 17 sample. Neither LNDD nor USADA would claim that the T/E ratio results should stand alone as proof of a positive test. However, LNDD's T/E results are reliable and provide strong evidence to corroborate the IRMS findings. As noted at paragraphs 33a, 33c, 118 of USADA's Pre-Hearing Brief, the CAS panels in both Susin and Wium considered T/E ratio results corroborating evidence even though the T/E results in those cases would not stand alone as adverse analytical findings because of B sample deterioration. Although Respondent's T/E ratio results are not being offered as an Adverse Analytical Finding under the ISL, USADA will nonetheless address Respondent's arguments which go to the reliability of the T/E ratio evidence.

49. In relation to Respondent's introductory comments on the T/E ratio test, the Panel should note that depending on the timing of both the exogenous testosterone administration and the time of sample collection, an athlete's testosterone level (or T/E ratio) may not show an increase. This is because exogenous testosterone administration causes natural production of testosterone to be suppressed.

50. In its Pre-Hearing Brief starting at paragraph 9, USADA provided the Panel with an accurate chronology including the sequence in which T/E ratio analysis was performed on Respondent's samples.

51. USADA addressed Respondent's non-forensic correction of documents issue starting at paragraphs 108 and 146 of its Pre-Hearing Brief. USADA's position on that issue will not be rehashed here, except to emphasize two points. First, only in two instances did non-forensic corrections involve IRMS chain of custody. Those corrections are discussed in paragraph 25 of this brief. Second, even assuming for argument's sake that the forensic correction provision of ISO applies (despite the clear omission of any forensic correction requirement in Articles 5.3.7 through 5.3.14 of the ISL, as discussed starting at paragraph 146 of USADA's Pre-Hearing Brief), USADA will be able to demonstrate through LNDD witnesses that none of the non-forensic corrections identified by Respondent caused Respondent's positive IRMS test result or the corroborating T/E results.

52. If Respondent is correct in concluding that the part of the Doping Control Form listing the athlete's medical declarations is "ipso facto," a violation of the International Standard for Testing, then that standard has been violated for virtually every sample collected since WADA was created. For example, even the laboratory's copy of the Doping Control Form

used by WADA when it collects samples includes the athlete's medical declarations. (Exhibit 108)

53. As discussed starting at paragraph 143 of USADA's Pre-Hearing Brief, Respondent is incorrect in claiming that LNDD used the same method for T/E screening and confirmation. Respondent is also incorrect in claiming that LNDD violated the ISL by identifying only one diagnostic ion with a relative abundance greater than 5%. The LNDD laboratory acquired three diagnostic ions – m/z 432.4, 417.3 and 209.3 – for testosterone and epitestosterone as required by the ISL. (See USADA Exhibit 24, USADA 0080-0083.) These are the same three diagnostic ions used by UCLA and other WADA-accredited laboratories. The WADA TD2003IDCR states that:

> "Selected Ion Monitoring Mode. In some cases, it may be necessary to monitor selected ions in order to detect the substance at the Minimum Required Performance Limits. When selected ions are monitored, at least three diagnostic ions must be acquired ...."

(USADA Exhibit 12) (The reference to 3 ions greater than 5% refers to the spectrum. Ions 432, 417 and 209 are all greater than 5%.)

54. As noted at paragraph 12 in the chronology in USADA's Pre-Hearing Brief, LNDD performed a second screen on the A sample after it had successfully completed the confirmation analysis on that sample. Respondent claims that LNDD "lost" one of the internal standards in performing that second screen. Respondent's claim is incorrect because LNDD re-injected a sample prepared using the confirmation extraction procedure (only methyltestosterone) into the screening instrumental procedure. The purpose of this analysis was to verify the observation in the first confirmation run that low counts were "linked to the inhibitor of derivatization observed in screen?" (USADA Exhibit 24, USADA 0191). The instrumental

screening method monitors for the inhibitor; the instrumental confirmation method does not. Since only methyltestosterone was added to the sample in the confirmation extraction procedure, it is the only internal standard expected in the results.

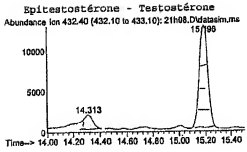
55. Respondent's "connect the dots" approach to creating a calibration curve is not good science and is certainly not required by the ISL or TD2004EAAS. The LNDD calibration curves shown, for example, on USADA Exhibit 24, USADA 0088 and 0089, are the product of a linear regression analysis which calculates the best straight line through the data points. There are statistical tests to evaluate the "goodness of fit" of the line. One such test is the "Coef of Det(r^2)" shown at the bottom left of the frame. The coefficient of 0.992 should be regarded as an excellent fit.

56. As clearly stated in TD2004EAAS (USADA Exhibit 9), the T/E ratio is computed from the areas or heights of the testosterone and epitestosterone peaks, not the ratio of concentrations. The inclusion of positive controls at known concentrations of testosterone and epitestosterone is not required by the ISL or TD2004EAAS.

57. Respondent's sample degradation argument was discussed at length in USADA's Pre-Hearing Brief starting at paragraph 140. Respondent's entire argument as set forth in his Pre-Trial Brief rests on the assumption that the instrument measured epitestosterone accurately at 0.44 ng/ml. The GC/MS instrument is programmed to report a value for every substance of interest, regardless of whether or not that value is above or below the instrument's reliable detection limit. Neither LNDD nor any other responsible laboratory would rely on a 0.44 ng/ml measurement of epitestosterone by GC/MS. LNDD does not (and is not required to) go back and attempt to edit or editorialize on what the instrument reports.

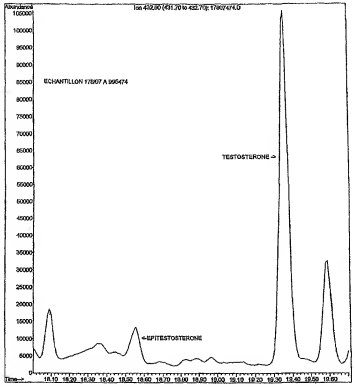
58. Respondent's Pre-Trial Brief regarding retention time issues refers exclusively to the first T/E confirmation analysis. This analysis was rejected by LNDD because of the low value for the internal standard (methyltestosterone) showed inhibition of derivatization caused by another substance in Respondent's urine. It makes no sense to discuss shifting retention times in an analysis that LNDD rejected at the time.

59. Respondent makes two arguments in comparing the A screen T and E chromatograms to the A and B confirmation T and E chromatograms. As USADA pointed out starting at paragraph 143 of its Pre-Hearing Brief, the reason the T/E ratio reported in the first and second A sample screens (4.9 and 5.1) is lower than the T/E ratio reported in the A and B sample confirmations (11.4 and 11.0) is because the epitestosterone value reported in the screens is inflated by a coeluting peak. Simply put, any experienced laboratory director would see visually that the reported E value in the screens (USADA 0055 and USADA 0058 (USADA Exhibit 24)) is too high, therefore making the reported T/E value too low. The screens are inaccurate, but inaccurate in a way that favors Respondent. Respondent argues that the coeloting peak could not be an explanation for the difference between the screen and confirmation results because the coelution is the same in the screen and confirmation peaks. That is simply not true. As can be seen on USADA Exhibit 26, LNDD 0027-0035 which are enlarged presentations of the B sample confirmation epitestosterone and testosterone peaks, although considerable background is still visable, the confirmation chromatograms show a better (i.e., narrower) peak shape. For comparison, the chromatogram of the second screen and an enlargement of the B confirmation chromatogram are presented below:



A Sample Screen
USADA Exhibit 24, USADA 0055

```
File          : D:\MSD20\JUIL06\2407\17807474.D
Operator      : 28
Acquired      : 24 Jul 2006  13:28      using AcqMethod MAN27
Instrument    :
     MSD 20
Sample Name: 178/07 995474 ta
Misc Info     :
Vial Number: 4
```



B Sample Confirmation
USADA Exhibit 26, LNDD 0034

The consistency of the results of the A and B confirmation also supports the area for epitestosterone allocated by the instrument. Again, anything that makes the epitestosterone peak appear to be larger than it really is would lower the T/E ratio in the athlete's favor. (Higher E means lower T/E ratio.)

60. WADA Technical Document TD2004EAAS expressly provides that "[t]he comparison of screening results and confirmed results is acceptable." (USADA Exhibit 9, paragraph 5). This is logical because only those athlete samples with a T/E ratio greater than 4 ever go through confirmation analysis. Respondent responds by arguing that screening results from other samples should not be used in a longitudinal analysis because his own sample demonstrates the variability that can occur between T/E screening and confirmation methods. The answer to Respondent's argument is that in performing a longitudinal study it is important for the reviewing scientist to look at the chromatograms underlying the testosterone and epitestosterone screen results and to exclude those results where the chromatogram suggests that T or E may have been measured inaccurately. USADA has produced the T and E screen chromatograms for each sample included in its longitudinal study. A review of these chromatograms demonstrates that there are more than enough reliable screen results to produce a profile which establishes that Respondent's Stage 17 T/E ratio is clearly abnormal.

X. NO OVERLAP BETWEEN THE PERSONNEL CONDUCTING THE ANALYSIS OF THE A SAMPLE AND B SAMPLE.

Respondent has offered no new evidence on this issue other than to repeat his erroneous claim that Ms. Mongongu and Ms. Cerpolini performed some part of the B sample analytical procedure. This issue is discussed in USADA's Pre-Hearing Brief starting at paragraph 111.

USADA would also like to draw the Panel's attention to USADA v. Tammy Thomas, where the Panel held: "Acting as mere bottle movers of the sealed samples ... [is] not carrying out the analysis of the B sample" (Exhibit 109, page 8).

XI. CONCLUSION.

For all of the reasons set forth above, and included in USADA's Pre-Hearing Brief, USADA respectfully submits that the evidence clearly establishes that Respondent has committed an anti-doping rules violation.

Respectfully submitted this 3rd day of May, 2007.

United States Anti-Doping Agency

Richard R. Young
Matthew S. Barnett
Holme Roberts & Owen LLP
90 South Cascade Avenue, Suite 1300
Colorado Springs, CO 80903

Travis T. Tygart
General Counsel
1330 Quail Lake Loop, Suite 260
Colorado Springs, CO 80906

Attorneys for the United States Anti-Doping Agency

TABLE OF CONTENTS

I. INTRODUCTION 1

B. Respondent's Sample Testing Chronology. 4

C. Respondent's Introductory Arguments 8

II. BURDEN OF PROOF 9

A. The UCI Rules 9

B. The Presumption in Favor of WADA-Accredited Laboratories. 9

C. Alleged mistakes in connection with the analysis and documentation of Respondent's T/E ratio do not make the IRMS results "wholly meaningless." 11

D. The Comfortable Satisfaction Standard 12

III. LNDD'S SAMPLE BOTTLE CHAIN OF CUSTODY SATISFIES WADA CRITERIA 15

IV. RESPONDENT'S PRE-TRIAL BRIEF ADDS NOTHING TO DISCREDIT THE RELIABILITY OF LNDD'S ADVERSE ANALYTICAL FINDING BASED ON IRMS RESULTS 21

A. LNDD's Quality Controls. 21

B. There is no problem with LNDD using OS2 software. 21

V. LNDD IS ENTITLED TO RELY ON THE WADA POSITIVITY CRITERIA ESTABLISHED BY WADA IN TD2004EAAS. 26

VI. THE MONTREAL, COLOGNE, SYDNEY AND UCLA LABORATORIES WOULD REPORT RESPONDENT'S SAMPLE AS AN ADVERSE ANALYTICAL FINDING. 27

VII. UNCERTAINTY 30

VIII. LNDD'S ADVERSE ANALYTICAL FINDING FOR RESPONDENT'S STAGE 17 SAMPLE IS CORROBORATED BY THE FINDING OF EXOGENOUS TESTOSTERONE IN RESPONDENT'S OTHER TOUR SAMPLES. 33

IX. RESPONDENT'S STAGE 17 T/E RATIO AND HISTORICAL T/E VALUES CORROBORATE LNDD'S IRMS FINDING OF RESPONDENT'S EXOGENOUS USE OF TESTOSTERONE 42

X. NO OVERLAP BETWEEN THE PERSONNEL CONDUCTING THE ANALYSIS OF THE A SAMPLE AND B SAMPLE. 48

XI. CONCLUSION. 49

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this 3rd day of May, 2007, a true and correct copy of the foregoing **PRE-TRIAL RESPONSE BRIEF OF THE UNITED STATES ANTI-DOPING AGENCY** was served by Electronic Mail and Federal Express, as follows:

Richard H. McLaren, Esq.
Innovative Dispute Resolution, Ltd.
c/o McKenzie Lake Lawyers, LLP
300 Dundas Street
London, Ontario N6B 1T6
CANADA
E-mail: mclaren@mckenzielake.com

Christopher L. Campbell, Esq.
Chapman & Intrieri
2236 Mariner Square Drive,Ste. 300
Alameda, CA 94501
E-mail: ccampbell@chapmanandintrieri.com

Patrice M. Brunet, Esq.
1010 DeLa Gauchetiere West, #2260
Montreal, Quebec H3B2N2
CANADA
E-mail: Pbrunet@brunetavocats.com

Maurice M. Suh
Gibson, Dunn & Crutcher LLP
333 South Grand Avenue
Los Angeles, CA 90071-3197
Email: msuh@gibsondunn.com

Howard L. Jacobs, Esq.
5210 Lewis Road
Suite 5
Agoura Hills, CA 91301
Email: howard.jacobs@yahoo.com

Vicki Bing